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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,356

06/25/2007

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,356	Applicant(s) KOLOPP-SARDA ET AL.	
	Examiner Khatol S. Shahnian-Shah	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-12,14-19,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-11,18, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. The amendment filed 3/23/2010 has been entered into the record. Claims 3, 4, 6, 7 and 20 have been cancelled. Claims 1, 2, 5, 18, 19 and 22 have been amended. Specification page 1 has been amended.

Status of Claims

2. Claims 1, 2, 5, 8-11, 12, 14-19, 22 and 23 are pending. Claims 1, 2, 5, 8-11, 18, 22 and 23 are under examination. Claims 12 and 14-17 are withdrawn as being drawn to non-elected inventions.

Objections Withdrawn

3. Objection to the specification, made in paragraph 3 of the office action mailed 10/23/2009 in regard to sequence compliance is withdrawn in view of applicants' amendment filed 3/23/2010. The sequence listing and CRF are technically good and are entered into the database.

4. Objection to the specification, made in paragraph 5 of the office action mailed 10/23/2009 in regard to abbreviations is withdrawn in view of applicants' amendment filed 3/23/2010.

Rejections Moot

5. Rejection of claims 3, 4, 6 and 7 under 35 U.S.C. 112 second paragraphs, made in paragraph 9 of the office action mailed 10/23/2009 is moot in view of cancelation of said claims.

6. Rejection of claims 3, 4, 6 and 7 under 35 U.S.C. 102 (b), made in paragraph 11 of the office action mailed 10/23/2009 is moot in view of cancelation of said claims.

7. Rejection of claims 3, 4, 6 and 7 under 35 U.S.C. 102(e), made in paragraph 12 of the office action mailed 10/23/2009 is moot in view of cancelation of said claims.

Rejections Withdrawn

8. Rejection of claims 1, 2, 5, 8-11, 18, 22 and 23 under 35 U.S.C. 112 second paragraphs, made in paragraph 9 of the office action mailed 10/23/2009 is withdrawn in view of applicants' amendment filed 3/23/2010.

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9. Rejection of claims 1, 2, 5, 8-11, 18, 22 and 23 under 35 U.S.C. 102 (b), made in paragraph 11 of the office action mailed 10/23/2009 is withdrawn in view of applicants' amendment filed 3/23/2010.

10. Rejection of claims 1, 2, 5, 8-11, 18, 22 and 23 under 35 U.S.C. 102 (e), made in paragraph 12 of the office action mailed 10/23/2009 is withdrawn in view of applicants' amendment filed 3/23/2010.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 5, 8-11, 18, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margolin et al. WO 02/058721 A1 (prior art of record), and further in view of Colona et al. US 2003/0165875A1

The claims are drawn to a method of diagnosing disease of bacterial or fungal origin in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject, comparing level to a control population and correlating the result with presence or absence of disease.

Margolin et al. teach a method of diagnosing disease in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject (see abstract, claims specially claims 26, 31, 32 and 36 and pages 19 and 20). Margolin et al. teach bacterial disease and sepsis such as toxic shock, see page 44. Margolin et al. teach limitations of claims 18 and 19 see page 19. Margolin et al. teach immunochemical techniques (limitation of claims 22 and 23) see page 20. Margolin et al. do not teach comparing the level with a control. However, this deficiency has been overcome by the teachings of Colona et al.

Colona et al. teach a method of diagnosing disease of bacterial or fungal origin in a subject, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject (see abstract and claims). Colona et al. teach TREM -1 receptor as a specific marker for bacterial and fungal sepsis (see abstract and page 26), immunochemical techniques (see page 27, paragraph 0247), anti bodies specific for TREM-1 ligand and receptor (see page 26 and paragraph 0246), and blood and plasma from human (see paragraph 0244). Colona et al. teach sepsis (see paragraphs 0069, 0070, 0168,

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figures 19A-19D and fig 20). Colona et al. teach pulmonitis and pneumonia (see paragraph 0274). Colona et al. teach soluble TREM-1 (see paragraph 0274-0275, 0278, 0281 and fig 20, 21A-21C). Colona et al. teaches comparing the level with a control (see paragraph 0069).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Margolin et al. and Colona et al. to develop a method of diagnosing disease of bacterial or fungal origin in a subject. i.e. sepsis or pneumonia, which method comprises the step of measuring the level of sTREM-1 in a biological sample obtained from said subject, comparing level to a control population and correlating the result with presence or absence of disease. It would have been also obvious for one of ordinary skill in the art at the time the invention was made to use sTREM-1 as a marker for diagnosing bacterial or fungal infection in view of the teachings of either reference indicating that TREM-1 is upregulated as a result of such infection.

Conclusion

13. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnian-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

/Khatol S Shahn-Shah/
Examiner, Art Unit 1645
June 17, 2010